

REMARKS

This is in response to the Office Action dated March 23, 2006. Claims 3, 4, 14, 15, 18-22, 29, 30, 34, 36, 40, and 51-70 are pending in the above-referenced patent application. Applicants respectfully request further consideration of these claims in view of the following remarks.

The Office Action Summary incorrectly states the status of the pending claims, in that it does not include claims 64-70. These claims were filed in Preliminary Amendment A dated November 22, 2005, at the same time as then new claims 51-63. Clarification and examination of these claims on the merits is respectfully requested.

Election/Restrictions:

The Office action has indicated that the newly submitted claims 51-63 are directed to an invention that is independent or distinct from the invention originally claimed. The Examiner asserts that these "claims were not presented in the original restriction requirement and represent a new and distinct invention". Office action also asserts that Applicants made a constructive election of "the originally presented invention" and that claims 51-63 are withdrawn from consideration as being directed to a non-elected invention. *See* paragraphs 3 and 4 at pages 2-3 of the Office action.

Applicants respectfully traverse the Office's position with regard to the election/restriction of claims 51-63 as filed in Preliminary Amendment A on November 22, 2005, as well as the asserted constructive election of invention. Reconsideration thereof is hereby requested for the reasons set forth herein.

Claims 51-63

Claims 51-63 (as well as claims 64-70) were originally presented before any action on the merits. These claims were presented in Preliminary Amendment A filed on November 22, 2005 together with a response to the Restriction Requirement dated August 22, 2005. Hence, these claims were presented in response to restriction and before any action on the merits. As such, there is no factual basis for the Examiner's assertion that "the claims were not presented in the original restriction requirement."

Claims 51-63 are directed to the elected invention. In response to the aforementioned restriction, Applicants elected Group II claims 3, 4, 14, 15, 18-22, 29, 30, and 51-70 directed to pharmaceutical compositions comprising cation-binding core-shell particles. Claims 51-63 are likewise each directed to pharmaceutical compositions comprising cation-binding core-shell particles. Hence, there is no basis for asserting that these claims are drawn to a nonelected invention.

Further, there has not been any constructive election. The Examiner relies on the (incorrect) assertion that “applicant has received an action on the merits” to justify the postulated constructive election. In fact, as noted above, each of claims 51-63 (as well as claims 64-70) were presented in response to restriction and before any action on the merits. Therefore, the asserted “constructive election” is in error, and the withdrawal of claims 45 through 60 from consideration was improper. *See* 37 C.F.R 1.142(a).

Applicant respectfully requests the Office to reconsider the withdrawal of claims 51-63, and to consider claims 51-63 on the merits in a new supplemental non-final Office action, in view of the remarks herein.

Claims 34, 36 and 40

The Office has also withdrawn from consideration claims 34, 36, and 40. Applicant had previously requested reconsideration of the restriction of Group III claims 34, 36, and 40 from those of the elected Group II. *See* Preliminary Amendment A filed November 22, 2005 in Response to Restriction. The instant Office action does not appear to respond to such request. Accordingly, Applicant respectfully requests clarification of and a response to its previous request for reconsideration of the restriction requirement.

Claim Rejections – 35 USC § 112 (Written Description):

The Office has rejected claims 3, 4, 14, 15, 18-22, 29, and 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Office action asserts that “potassium binding polymers are not mentioned in the specification by name or exemplified by the examples.”

Applicants respectfully traverse the rejection for the reasons presented below.

Independent claim 3 has been previously amended to require potassium ion as a target solute, to characterize the core component as comprising a potassium-binding cation exchange polymer, to characterize the shell component as comprising a crosslinked polymer having a higher permeability for potassium ion than for one or more competing cations (e.g., Mg⁺⁺, Ca⁺⁺), and having a thickness ranging from about 0.002 microns to about 50 microns. *See* Preliminary Amendment A filed November 22, 2005.

Generally, the specification describes core-shell compositions that bind target solutes, and describes a preferred embodiment of a target solute as being potassium. See paragraphs [0009] and [0015]. Further potassium binding polymers are clearly and unambiguously described in the

specification, include cation exchange polymers having acid functional groups (e.g., carboxylate, phosphonate, sulfate, sulfonate, sulfamate, and combinations thereof). See paragraph [0056].

More particularly, support for the amendments to the claims and for the new claims can be found throughout the as-filed claims, specification and figures, including for example and without limitation: in paragraphs [0008], [0009], [0013] and [0014] (generally); and in paragraphs [0015] and [0019] (target solute); in paragraph [0018] (competing solute); in paragraphs [0022] and [0056] (core component); in paragraphs [0035] and [0037] through [0041] (shell component); in paragraph [0046] (shell thickness); in paragraphs [0023] through [0034] and [0036] (permeability/permselectivity); and in paragraphs [0066] and [0071] (indications).

See also original, as-filed claims of the application directed to pharmaceutical compositions (claims 1-33 and 47-50) and to methods of treatment (claims 34-46), including especially as-filed claim 3 and claims depending therefrom, such as claim 9 (potassium ion), claim 10 (relatively permeability), and claim 30 (removing potassium from the gastrointestinal tract).

Thus, a person of ordinary skill would have readily understood that Applicants were in possession of the invention as defined by the presently pending claims. Accordingly, Applicants respectfully request withdrawal of this rejection.

Claim Rejections – 35 USC § 103:

The Office has rejected claims 3, 4, 14, 15, 18-22, 29, and 30 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Tyler et al. (US 2004/0166156) and Bandi (USPN 4,902,501). See paragraphs 8 through 11 at pages 3-4 of the Office action.

Applicants respectfully traverse the above rejection. To establish a *prima facie* case of obviousness, “the prior art reference (or references when combined) must teach all or suggest all the claim limitations.” MPEP2143. The combination of the disclosures of Tyler et al. and Bandi do not teach all the requirements of the inventions as claimed.

Tyler et al.

Tyler et al. do not disclose a pharmaceutical composition comprising a core-shell particle with a core component comprising a cation exchange resin. Rather, *Tyler et al.* disclose a coated tablet. The coated tablet is disclosed as having a tablet core comprising an aliphatic amine polymer resin, and a water-based coating. See paragraph [0007]. The disclosed aliphatic amine polymers are said to be ion exchange resins that are useful to bind phosphate and/or as cholesterol lowering agents (e.g., as a bile

acid binder). *See* paragraphs [0002] and [0007] of *Tyler et al.* Hence, *Tyler et al.* disclose only an anion exchange resin as a tablet core.

The Office's reliance on the disclosure in Applicants own specification is misplaced. Although the instant specification discloses amine polymers as core components of core shell particles, the specification is abundantly clear that such embodiments are directed to applications involving anion (e.g., phosphate ion) binding – not to applications involving cation (e.g., potassium ion) binding. A person of ordinary skill in the art would readily understand that Applicants' specification involves different embodiments for different target solutes. *See* for example, paragraph [0015] in which anionic target solutes (including phosphate ions) are delineated separately from cationic target solutes (including potassium ions). In fact, the specification teaches that the core component comprises polymers selected to have functional groups with specific binding properties for a given particular target solute. *See* paragraph [0022] and [0056] of the specification. In this regard, amine functional polymers are disclosed specifically for use as core components of anion binding materials. *See* paragraph [0056]. In contradistinction, cation exchange polymers disclosed for use as core components include polymers with acid functional groups, such as carboxylate, among others. *See* paragraph [0056]. As such, the Examiner's rationale in relying on Applicant's own specification for the position that the amine polymers disclosed in *Tyler et al.* are cation exchange resins is without factual basis.

Further, and contrary to the position asserted in the Office action, *Tyler et al.* do not inherently disclose the removal of potassium ion. The Office action asserts that polyallylamine polymers disclosed by *Tyler et al.* would inherently also bind potassium. However, this position is technically inaccurate and legally insufficient. The Office does not set forth any reason why an amine polymer, the amine functional groups of which are provided in an ammonium salt form or which protonate *in vivo* to an ammonium salt form, would bind potassium. Both ammonium ion and potassium ion are positively charged ions. As such, there is no technical basis to assert an inherent binding. In fact, the electronic properties of such ions would lead to just the opposite – not to any direct association. Since the Office action does not set forth any rationale or extrinsic evidence, it does not set forth a *prima facie* basis establishing the asserted inherency. *See* MPEP §2112. The law is clear that the Examiner must demonstrate that "the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *See* In re Best, 195 USPQ 430 (CCPA 1977) (emphasis in original); Continental Can Company USA, Inc. v. Monsanto Co., 20 USPQ2d 1746 (Fed. Cir. 1991); *See also* Hansgirg v. Kemmer, 40 USPQ 665, 667 (CCPA 1939) (stating that "(i)nherency may not be established by probabilities or possibilities," but rather, must be based on a "natural result flowing from the operation as taught."). Hence, the asserted inherency basis for the instant rejection is improper.

Bandi does not make up for the deficiencies of Tyler *et al.* in this regard.

Accordingly, the Office action does not establish *prima facie* obviousness. Applicants respectfully request the withdrawal of this basis for rejection.

Provisional Double Patenting:

The Office action provisionally rejects claims 3, 4, 14, 15 and 18-22 on the ground of nonstatutory obvious-type double patenting over certain claims of co-owned, co-pending US Ser. No. 10/813,872. *See* paragraphs 12-14 at page 5 of the Office action.

Applicants acknowledge the provisional double patenting rejection. Applicants believe that the referenced claims of the instant applications are patentably distinct, in view of specific requirements recited therein. Nonetheless, Applicants will consider filing a terminal disclaimer to obviate this basis for rejection when the application is otherwise in condition for allowance.

CONCLUSION

It is submitted that the present application is in form for allowance, and such action is respectfully requested.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 29329-715.201). A duplicate copy of this paper is enclosed.

Respectfully submitted,

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